P. 06/14

Application No.: 10/057,606

Docket No.: 22106-00038-US1

REMARKS

Claims 21-47 are now in the application. The indication that claims 36-39 and 42 contain allowable subject matter is hereby noted.

Attached is a copy of a Revocation of Power of Attorney and a Statement under 37 CFR § 3.73(b) that were previously filed. Please make certain that all future correspondence is sent to the undersigned.

Claims 21-35, 40, 41 and 43-47 were rejected under 35 USC 103(a) as being unpatentable over US Patent 6,521,717 to Itoh alone or in view of US Patent 5,883,199 to McCarthy. The cited references do not render obvious the present invention.

Itoh suggests a binary mixture of an aromatic-aliphatic polyester like component A of the invention and an aliphatic polyester like component B of the invention. However, such binary mixture fails to provide a biodegradable polymer composition with the desired balance of mechanical and optical properties as achievable by the present invention.

Itoh fails to suggest employing a polyactic acid (Component C) as recited in the present claims.

The conclusion in the Office Action that the motivation to combine an aliphatic polyester (Component B) with polylactic acid (Component C) "is provided by the teaching of Itoh that either one can be used to improve the tensile strength and biodegradation of aromatic-aliphatic polyester" is in error.

Contrary to the assertion made in the Office Action, Itoh does not teach that polylactic acid (Component C) "can be used to improve the tensile strength and biodegradation of aromatic-aliphatic polyester (Component A)". Itoh does not contain any reference to polylactic acid. Lactic acid is the 2-hydroxypropionic acid of formula CH₃-CHOH-COOH. Itoh suggests several methods to obtain the aliphatic polyester B, including the condensed polymerization of hydrocarboxylic acids or esters thereof, namely the method ii) of column 6, lines 29-30, and lines

Docket No.: 22106-00038-U\$1

49-57. A list of several hydroxycarboxylic acids or esters thereof is given, including 3-hydroxypropionate, 3-hydroxy-2,2-dimethylpropionic acid, but the 2-hydroxypropionic acid is not included in such list. Therefore, a skilled person would have not been motivated to use polylactic acid in combination with Component A of Itoh, since polylactic acid was excluded from the list of hydroxycarboxylic acids suggested by Itoh. Itoh suggests combining an aliphatic-aromatic polyester A with an aliphatic polyester B which can contain a number of hydroxycarboxylic acid moieties, but not that of lactic or polylactic acid.

In fact, since lactic acid is conspicuously absent from the listing of hydroxypropionic acids in Itoh, if anything, Itoh actually teaches away from the present claims.

Moreover, the tensile strength referred to in the Office Action is not relevant to the present claims since "tensile strength" and "tear resistance" are not the same thing. It is tear resistance for which unexpected results have been shown. Tensile strength and tear resistance are not interrelated. Moreover, tensile strength is not even a property or parameter discussed in the present specification.

With respect to tear resistance as discussed in our prior response, typical properties of binary mixtures of the kind A+B are given in Table 2 of the specification as comparative examples 3a-3d. The main drawback is the strong anisotropic behavior as to tear resistance of a film in the longitudinal and transverse directions. This is reflected by the Elmendorf test, particularly by the ratio E_{cross}/E_{long} . When the film is not anisotropic, the values of E_{cross}/E_{long} do not differ significantly and their ratio is close to 1 (see values of Table 1). In contrast, when the values differ greatly, the ratio of E_{cross}/E_{long} is quite remote from 1, as reported in Table 2 with respect to comparative examples 3a-3c (in example 3d such value was even not measured), where it varies from 27.8 to 35.7. This strong anisotropy represents a significant drawback in the use of the film, as appreciated by those persons skilled in the art. The above drawback is overcome by the ternary mixture of the present invention. Moreover, Itoh's preferred aliphatic polyesters (B) are obtained from aliphatic dicarboxylic acids with 2 to 6 carbon atoms (see column 6, lines 24-26), while the preferred diacids according to the present invention have more than 5 carbon atoms.

Docket No.: 22106-00038-US1

McCarthy fails to overcome the above deficiencies of Itoh with respect to rendering obvious the present invention. McCarthy suggests a binary mixture of polylactic acid like component C of the invention and aliphatic polyesters like component B of the invention. However, such binary mixture fails to provide a biodegradable polymer composition with the desired balance of mechanical and optical properties as achievable by the present invention. Typical properties of binary mixtures of the kind B+C are given in Table 2 as comparative examines 1a-1c. The main drawback is the poor tear resistance in both the longitudinal and transverse direction as reflected by the Elmendorf test. Both E_{cross}/E_{long} are always less than 11, and in most cases less than 9, while the mixture of the present invention shows substantially higher values.

It was not obvious, and therefore, not expected, that a ternary mixture of A+B+C would have been capable of producing films in which the strong anisotropy of mixtures A+B disappears without retaining the low tear values in the longitudinal and cross directions typical of mixtures B+C. In other words, a person skilled in the art was confronted with the following dilemma: either accept the anisotropy of binary mixtures A+B, or accept the poor tear resistance of binary mixtures B+C. The art fails to suggest making a mixture of A+B+C, since it could have resulted in a combination of anisotropy and low tear values. In contrast, the mixtures of the invention surprisingly offer a good balance of both properties, together with good optical properties (transparency) and biodegradability.

The Examiner also opined that, alternatively, the motivation to combine an aliphatic polyester (Compound B) with polylactic acid (Compound C) "is provided by the teaching of McCarthy that blends of aliphatic polyester with polylactic acid and have good tensile strength, stiffness and elongation properties".

This basis is not sustainable since, as mentioned above, tensile strength is not the same as tear resistance and is not the property upon which the unexpected results is based.

Moreover, the problem or issue to solve was not merely combining B and C, but rather whether combining A, B and C is motivated by McCarty. However, it is abundantly clear that

Docket No.: 22106-00038-US1

McCarty is totally silent about whether or not component B and component C of McCarty can be combined with the aromatic-aliphatic polyester component A with affecting the balance of properties discussed in the present application. Clearly Itoh also fails to say anything that motivates such combination.

The art does not provide any suggestion that the problems addressed would or could be overcome by the mixture of the present invention. The art lacks the motivation to combine McCarthy with Itoh in order to overcome the problems of the prior art.

The conclusion in the Office Action that the evidence is not commensurate to the scope of the claims is not deemed tenable. For instance, the showing of unexpected results is not limited to a comparison between the ternary mixtures of the invention with the binary mixtures of Itoh. Binary mixtures of A and B like those of Itoh are dealt with in comparative examples 3a, 3b, 3c and 3d of Table 2. However, comparative examples 1a, 1b and 1c of Table 2 related to binary mixtures of B and C like those of McCarty. Therefore, the showing of unexpected results is given with reference to binary mixtures of both types, A + B and B + C. Moreover, the ranges of compositions claimed are well supported by the examples. The showing is based on properties measured on films but clearly these are due to and originated by the chemical nature of the mixture in terms of its composition of matter.

It is well settled that properties need not be recited in the claims to be considered when evaluating non-obviousness. The properties of the subject matter and improvements which are inherent in the claimed subject matter and disclosed in the specification are to be considered when evaluating the question of obviousness under 35 USC 103. See *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d. 1923 (Fed. Cir. 1990), *In re Antonie*, 195, USPQ 6 (CCPA 1977), *In re Estes*, 164 USPQ (CCPA 1970), and *In re Papesch*, 137 USPQ 43 (CCPA 1963).

In re Papesch, supra. is especially instructive on this point. In Papesch, the claims were drawn to compounds defined just by their structural formula. The claims under consideration did not recite any properties or characteristics of the claimed compound. However, in order to establish patentability over the prior art, the Applicant presented evidence to establish that the

Docket No.: 22106-00038-US1

claimed compounds possessed unexpectedly potent anti-inflammatory activity in contrast to the prior art compounds. The claims were found to be patentable based upon the anti-inflammatory activity of the compounds, even though that property was not explicitly stated in the claims.

The situation in the present case is not unlike that in *Papesch* whereby an unexpected property of tear resistance has been established, and pursuant to *Papesch*, it need not be recited explicitly in the claims.

Also, no property can be ignored in determining patentability and comparing the claimed invention to the cited art. Along these lines, see *In re Papesch*, supra, *In re Burt et al*, 148 USPQ 548 (CCPA 1966), *In re Ward*, 141 USPQ 227 (CCPA 1964), and *In re Cescon*, 177 USPQ 264 (CCPA 1973).

Furthermore, the cited art lacks the necessary direction or incentive to those or ordinary skill in the art to render the rejection under 35 USC 103 sustainable. The cited art fails to provide the degree of predictability of success of achieving the properties attainable by the present invention needed to sustain a rejection under 35 USC 103. See Diversitech Corp. v. Century Steps, Inc. 7 USPQ2d 1315 (Fed. Cir. 1988), In re Mercier, 185 USPQ 774 (CCPA 1975) and In re Naylor, 152 USPQ 106 (CCPA 1966).

Moreover, the mere fact that the cited art may be modified in the manner suggested by the Examiner does not make this modification obvious, unless the cited art suggests the desirability of the modification. No such suggestion appears in the cited art in this matter. The Examiner's attention in kindly directed to *In re Lee* 61 USPQ2d 1430 (Fed. Cir. 2002) *In re Dembiczak et al.* 50 USPQ2d. 1614 (Fed. Cir. 1999), *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984), *In re Laskowski*, 10 USPQ2d. 1397 (Fed. Cir. 1989) and *In re Fritch*, 23, USPQ2d. 1780 (Fed. Cir. 1992).

In Dembiczak et al., supra, the Court at 1617 stated: "Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis

Docket No.: 22106-00038-US1

is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., C.R. Bard, Inc., v. M3 Sys., Inc., 157 F.3d. 1340, 1352, 48 USPQ2d. 1225, 1232 (Fed. Cir. 1998) (describing 'teaching or suggestion motivation [to combine]' as in 'essential evidentiary component of an obviousness holding'), In re Rouffet, 149 F.3d 1350, 1359, 47 USPQ2d. 1453, 1459 (Fed. Cir. 1998) ('the Board must identify specifically...the reasons one of ordinary skill in the art would have been motivated to select the references and combine them');...".

The rejection of the claims seems to be in the nature of the impermissible standard of "ought to be tried." See <u>Jones v. Hardy</u>, 727 F.2d 1524, 220, USPQ 1021 (Fed Circ. 1984).

In view of the above, consideration and allowance are, therefore, respectfully solicited.

In the event that the Examiner believes an interview might serve to advance the prosecution of this application in any way, the undersigned attorney is available at the telephone number noted below.

The Commissioner is hereby authorized to charge any fees or credit any overpayment associated with this communication including any extension fees to Deposit Account No. 22-0185.

Respectfully submitted,

Dated: April 6, 2004

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